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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,238	10/12/2001	David A. Basiji	BIOL0029	9708

25268 7590 09/17/2003

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EXAMINER

TRAN, MY CHAU T

ART UNIT PAPER NUMBER

1639

DATE MAILED: 09/17/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/976,238

Applicant(s)

BASIJI ET AL.

Examiner

My-Chau T. Tran

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,8-12 and 41-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8-12 and 41-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1639

DETAILED ACTION

1. Applicant's amendment filed 7/11/03 in Paper No. 15 is acknowledged and entered.

Claims 3-7 and 13-40 are canceled by the amendment. Claims 1 and 8 are amended by the amendment. Claims 41-48 are added by the amendment.

2. Claims 1-2, 8-12, and 41-48 are pending.

Priority

3. Applicant did not provide any clarification as requested in the previous Office Action regarding the foreign application (Application # 0019744.2, England), which has been placed of record in the file. It is noted on 4/18/03 Mr. Michael King (an attorney of record) called the examiner and requested that a fax copy be sent to him of the foreign application in question. A fax copy was sent to Mr. Michael King. Appropriate clarification/correction is required.

4. Claims 1-2, 8-12, and 41-48 are treated on the merit in this Office Action.

Withdrawn Rejections

5. The previous rejections 35 USC 112, second paragraph, for claims 1-2, and 8-12 have been withdrawn in view of applicant's amendments of claims 1 and 8 and the addition of new claims 41-48.

Art Unit: 1639

6. The previous rejections under 35 USC 102(b) as being anticipated by Dower et al. (US Patent 5,708,153) for claims 1, 8 and 10-12 have been withdrawn in view of applicant's amendments of claims 1 and 8.

7. The previous rejections under 35 USC 102(b) as being anticipated by Zarling et al. (US Patent 5,674,698) for claims 8-9, and 11 have been withdrawn in view of applicant's amendments of claims 1 and 8.

Maintained Rejections

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

9. Claims 1-2, 41-44 (*new claims*) are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (US Patent 5,922,617).

"The presently claimed invention recites a method of constructing a library of optically distinct reporter labeled carriers. The method steps comprise of providing a plurality of optically distinct reporter, a plurality of carriers, and a plurality of reaction vessels, wherein each vessels is assigned a predetermined combination of a carrier and a reporter and does not contains a mixture of different optically distinct reporter labeled carriers. The reporter is attached to the carrier a physical attachment or a chemical attachment."

Wang et al. disclosed a method of preparing a microarray (library) that comprise of beads (carriers) and bound components wherein the bound components comprise of a label such as a

Art Unit: 1639

fluorescent label (optical reporters) (col. 5, lines 10-13, and 60-64; col. 7, lines 60-67). The bound component can be directly bound (chemical attachment) or indirectly bound (physical attachment) to the beads (referring to the attaching step) (col. 5, lines 60-64; col. 3, lines 17-30). The arrays employ individual segments (reaction vessels) wherein each segments contains different particles carrying bound components (referring to claims 1d) and 2) (col. 6, lines 21-32; col. 14, lines 35-59). Therefore, the method of Wang et al. anticipates the presently claimed invention.

Additionally, Wang et al. disclose that the carrier can be optically distinguished from carriers in other segments based on size (refers to claim 41) or shape (refers to claim 42) (col. 13, lines 61-67 to col. 14, lines 1-12). The carrier can be optically distinguished from carriers in other segments based on color (refers to claim 43) or intensity of color (refers to claim 44) due to the type of reporter (col. 9, lines 17-20). Therefore, the method of Wang et al. anticipates the presently claimed invention.

Response to Arguments

10. Applicant's argument(s) directed to the above rejection under 35 USC 102(b) as being anticipated by Wang et al. (US Patent 5,922,617) for claims 1-2 were considered but they are not persuasive for the following reasons.

Applicant contends that (1) “[W]ang does not disclose that such reporters are attached to the beads *after* the bead is placed into the pit”; (2) “[W]ang does not teach that each bead in his array must have attached to it a set of optically distinct reporters that is uniquely different from the set of optically distinct reporters attached to each other bead in the array.” Applicant further argue that Wang et al. “[e]xplicitly refers to U.S. Patent No. 5,565,324” reporters (e.g. identifiers

Art Unit: 1639

for each bead) which are “*not optically distinct reporters*”. Therefore the method of Wang et al. does not anticipate the presently claimed method.

Applicant's arguments are not convincing since Wang et al. do not anticipate the presently claimed method. Wang et al. disclose the method of attaching the reporter to the bead (col. 5, lines 10-13, and 60-64; col. 7, lines 60-67). Whether the attachment of the reporter to the bead occur before or after the bead is place into the “vessel” would be a choice as experimental design and is considered within the purview of the prior art because the order of the method steps would not change the result of the complex for detection that is a bead that has a reporter attached. Wang et al. do disclose that a “set of bead” can be encoded by a reporter that are optically distinct from the reporter of another “set of bead” (col. 7, lines 60-67 to col. 8, lines 1-10; col. 9, lines 17-20). Further, Wang et al. do not explicitly refers the reporter of just U.S. Patent No. 5,565,324. Wang et al. disclose that ‘*For example, one may use a binary code of*’ U.S. Patent No. 5,565,324 (col. 7, lines 12-15) and ‘*Alternatively, one may use dots or stripes of fluorescent dyes, the same or different dyes, so as to create an address where one can define the site by the order of emission wavelengths, intensity, size, or the like*’ (col. 9, lines 17-20). Therefore, the method of Wang et al. does anticipate the presently claimed method.

Claim Rejections - 35 USC § 103

11. Claims 8-12, and 45-48 (*New Claims*) are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (US Patent 5,922,617) in view of Furka (WO 93/24517).

“The presently claimed invention recites a method of constructing a library of optically distinct reporter labeled carriers. The method steps comprise of providing a plurality of

Art Unit: 1639

optically distinct reporter, a plurality of optically distinct carriers, and a plurality of reaction vessels, wherein each vessels is assigned a predetermined combination of a carrier and a reporter and does not contains a mixture of different optically distinct reporter labeled carriers. The reporter is attached to the carrier by a physical attachment and a chemical attachment. The optically distinct reporter and the optically distinct carriers are distinguishable based on intensity, size, or shape."

Wang et al. disclosed a method of preparing a microarray (library) that comprise of beads (carriers) and bound components wherein the bound components comprise of a label such as a fluorescent label (optical reporters) (col. 5, lines 10-13, and 60-64; col. 7, lines 60-67). The bound component can be directly bound (chemical attachment) or indirectly bound (physical attachment) to the beads (col. 5, lines 60-64; col. 3, lines 17-30). The arrays employ individual segments (reaction vessels) wherein each segments contains different particles carrying bound components (optically distinct reporter labeled carrier) (col. 6, lines 21-32; col. 14, lines 35-59).

Additionally, Wang et al. disclose that the carrier can be optically distinguished from carriers in other segments based on size (refers to claim 45) or shape (refers to claim 46) (col. 13, lines 61-67 to col. 14, lines 1-12). The carrier can be optically distinguished from carriers in other segments based on color (refers to claim 47) or intensity of color (refers to claim 48) due to the type of reporter (col. 9, lines 17-20). Therefore, the method of Wang et al. anticipates the presently claimed invention.

The method of Wang et al. does not expressly disclose that the beads are optically distinct.

Art Unit: 1639

Furka disclosed a method synthesizing a sub-kit of peptide library bound to color and/or fluorescent support where the color, or the fluorescence, or the size or the specific gravity of the beads or combinations of these characteristics are assigned (pg. 10, lines 29-33). The support bound mixture can be screened without the use of expensive sequenators (pg. 19, lines 15-16).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include beads are optically distinct as taught by Furka in the method of Wang et al. One of ordinary skill in the art would have been motivated to include beads are optically distinct in the method of Wang et al. for the advantage of providing a support bound mixture can be screened without the use of expensive sequenators. Since both Wang et al. and Furka disclose a method of preparing a library of beads with bound components such as peptide (Wang: col. 6, lines 3-5 and col. 5, lines 7-9; Furka: pg. 10, lines 29-33).

Response to Arguments

12. Applicant's argument(s) directed to the above rejection under 35 USC 103(a) as being unpatentable over Wang et al. (US Patent 5,922,617) in view of Furka (WO 93/24517) for claims 8-12, and 41-44 (*New Claims*) were considered but they are not persuasive for the following reasons.

Applicant argues that the combination of Wang et al. and Furka would not disclose the presently claimed invention because “[W]ang does not disclose the steps of placing carriers in reaction vessels, placing reporters in reactions vessels, and then attaching the reporters to the carriers *in the reaction vessels*” and that “[W]ang does not disclose an array in which each element in the array (well, pit, reaction vessel) must include a unique set of optically distinct reporter labeled carriers that is uniquely different from the optically distinct reporter labeled

Art Unit: 1639

carriers of each other element in the array.” Therefore the combination of Wang et al. and Furka would not disclose the presently claimed invention.

Applicant’s arguments are not convincing since the combination of Wang et al. and Furka would disclose the presently claimed invention because Wang et al. do disclose the step of placing the carriers in the reaction vessels (col. 6, lines 21-26; col. 13, lines 42-50) and the method step of attaching the reporter to the bead (col. 5, lines 10-13, and 60-64; col. 7, lines 60-67). Whether the attachment of the reporter to the bead occur before or after the bead is place into the “vessel” would be a choice as experimental design and is considered within the purview of the prior art because the order of the method steps would not change the result of the complex for detection that is a bead that has a reporter attached. Wang et al. do disclose that a “set of bead” can be encoded by a reporter that are optically distinct from the reporter of another “set of bead” (col. 7, lines 60-67 to col. 8, lines 1-10; col. 9, lines 17-20). Therefore the combination of Wang et al. and Furka would disclose the presently claimed invention.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-2, 8-12, 43-44, and 47-48 rejected under 35 U.S.C. 102(b) as being anticipated by Still et al. (US Patent 5,565,324).

Still et al. disclose several different methods of combinatorial chemistry (col. 15, lines 14-37). The methods comprise of dividing the particles (carriers) into individual containers (col. 15, lines 18-26), and adding the identifier (reporter) that encode the reagent and reaction stage to the particles (col. 15, lines 27-29). In one method, the beads are recombined after each synthesis stage (e.g. split pool synthesis) (col. 15, lines 34-37). In another method, the beads are not recombined after each synthesis stage (col. 15, lines 41-46). The product of these syntheses comprises bead, and identifier (col. 3, lines 5-15; col. 8, lines 25-56; col. 10, lines 7-51). The identifiers comprise tags and are distinguished one from the other that would uniquely identify different reagent use and reaction stages (col. 31, lines 44-55; col. 26, lines 20-22). The resulting products are screen for desired property that includes chemical property such as fluorescent detection (e.g. color or color intensity) (col. 15, lines 62-64; col. 27, lines 15-28). Therefore, the method of Still et al. anticipates the presently claimed method.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1639

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on Increased Flex Schedule and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
September 16, 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER